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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Thomas M. Jessell et al.

Serial No : 10/002,278 Examiner: E.B. O'Hara

Filed : November 2, 2001 Group Art Unit: 1646

For : CLONING, EXPRESSION AND USES OF DORSALIN-1

1185 Avenue of the Americas
New York, New York 10036
March 14, 2003

Assistant Commissioner for Patents
Washington, D.C. 20231

SIR:

COMMUNICATION IN RESPONSE TO JANUARY 14, 2003 OFFICE ACTION AND PETITION FOR ONE-MONTH EXTENSION OF TIME

This Communication is submitted in response to a January 14, 2003 Office Action issued by the United States Patent and Trademark Office in connection with the above-identified application. A response to the January 14, 2003 Office Action was originally due February 14, 2003. Applicants hereby petition for a one-month extension of time. The required fee for a one-month extension of time for a small entity is FIFTY FIVE DOLLARS ($55.00) and a check for this amount is enclosed. A response to the January 14, 2003 Office Action is now due March 14, 2003. Accordingly, this Communication is being timely filed.

Restriction Requirement Under 35 U.S.C. §121

The Examiner required restriction to one of the following inventions under 35 U.S.C. §121:

I. Claims 1, 19 and 41-48 drawn to dorsalin-1 polypeptides, classified in class 530, subclass 350, for example;

II. Claim 20 drawn to a method for stimulating neural crest

cell differentiation comprising contacting a neural crest cell with dorsalin-1 polypeptide, classified in class 424, subclass 185.1, for example;

III. Claim 22 drawn to a method for regenerating nerve cells in a subject comprising administering a dorsalin-1 polypeptide, classified in class 514, subclass 2, for example;

IV. Claim 23 drawn to a method for promoting bone growth in a subject comprising administering a dorsalin-1 polypeptide, classified in class 514, subclass 2, for example;

V. Claim 24 drawn to a method for promoting wound healing in a subject comprising administering a dorsalin-1 polypeptide, classified in class 514, subclass 2, for example;

VI. Claims 25-27 drawn to a method for treating a neural tumor in a subject comprising administering a dorsalin-1 polypeptide, classified in class 514, subclass 2, for example;

VII. Claims 36-38 drawn to an antibody to dorsalin-1 polypeptide, classified in class 530, subclass 388.22, for example; and

VIII. Claim 39 drawn to a method for inhibiting the activity of dorsalin-1 polypeptide in a subject comprising administering an antibody to dorsalin-1 polypeptide, classified in class 514, subclass 2, for example.

The Examiner stated that the polypeptides of invention I are related to the antibodies of invention VII by virtue of being the cognate antigen, necessary for the production of the antibodies.

The Examiner stated that although the protein and antibody are related due to the necessary stearic complementarity of the two, they are distinct inventions because they are physically and functionally distinct chemical entities, and because the protein can be used in another and materially different process from the use for production of the antibody, such as in a pharmaceutical composition in its own right, or to assay or purify the natural receptor of the protein.

The Examiner stated that inventions I and inventions II-VI are related as product and process of use. The Examiner stated that the inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. §806.05(h)). The Examiner stated that in the instant case the polypeptide can be used in a method of making and purifying antibodies, which is a materially different method from those of methods II-VI. The Examiner stated that inventions II-VI are related in that they all require dorsalin-1 polypeptide, however the methods are patentably distinct because they are different methods of treatment having different results and goals.

The Examiner stated that invention VII and invention VIII are related as product and process of use. The Examiner stated that in the instant case the antibodies are used in the method for inhibiting the activity of dorsalin-1 in a subject, but the antibodies can also be used in a method of purifying the protein, which is a materially different method.

The Examiner stated that invention I and invention VIII are related as a process of making and a process of using a common product. The Examiner stated that the polypeptides of invention

I are the cognate antigens necessary for production of the antibody of invention VII which is used in the method of inhibiting the dorsalin-1 of invention VIII, but the polypeptide may also be used in a method of treatment, which is a materially different method.

The Examiner stated that invention VII and inventions II-VI are unrelated. The Examiner stated that inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP §806.04, MPEP §808.01). The Examiner stated that in the instant case the antibody to dorsalin-1 polypeptide is not used in the methods of inventions II-VI.

The Examiner stated that invention VIII is unrelated to each of inventions II-VI. The Examiner stated that the invention of method VIII requires antibody to dorsalin-1 polypeptide, which the invention of methods II-VI require the dorsalin-1 antibody.

Further Restriction Within Groups I-VIII:

The Examiner stated that applicants' claims are drawn to two patentably distinct dorsalin-1 polypeptide, chick dorsalin-1 (SEQ ID NO: 2) and mouse dorsalin-1 (SEQ ID NO: 9). The Examiner stated that these proteins are patentably distinct because they have significantly different amino acid sequences (427 amino acids for SEQ ID NO: 2 and 257 amino acids for SEQ ID NO: 9), and would require separate searches. Therefore, the Examiner stated that antibodies to the two different proteins are also different and patentably distinct, and the methods of using the two polypeptide or antibodies are also patentably distinct and would require different search and consideration. The Examiner required applicants to elect a single invention of dorsalin-1 polypeptide, antibody or method of treatment. The Examiner

advised applicants that this is not a species election.

The Examiner stated that because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their different classifications, recognized divergent subject matter and/or the need for non-coextensive literature search and/or separate sequence database searches, restriction for examination purposes as indicated is proper.

In response to this restriction requirement, applicants' undersigned attorney, on behalf of applicants, hereby elects, with traverse, to prosecute the invention of Examiner's Group I, i.e. claims 1, 19 and 41-48 drawn to dorsalin-1 polypeptides.

In addition, in response to this restriction requirement, applicants' undersigned attorney, on behalf of applicants, hereby further elects, with traverse, the mouse polypeptide as set forth in SEQ ID NO: 9.

Applicants note that 35 U.S.C. §121 states, in part, that "[i]f two or more independent and distinct inventions are claimed in one application, the Commissioner may require the application to be restricted to one of the inventions." [Emphasis added]. Applicants request that the restriction of Examiner's Group I from Examiner's Groups II to VIII be withdrawn in view of the fact that the claims of Examiner's Group I are not independent of Examiner's Group's II to VIII. Applicants maintain that the claims of Examiner's Group I and Examiner's Groups II to VIII do not define patentably distinct inventions.

Under M.P.E.P. §802.1, "independent" means "there is no disclosed relationship between the subjects disclosed, that is, they are unconnected in design, operation, and effect." The claims of Examiner's Group I drawn to dorsalin-1 polypeptides are related

to the claims of Examiner's Groups II to VIII in that the claims in all groups are related to dorsalin-1 polypeptides and uses thereof.

The claims of Group I, which are drawn to dorsalin-1 polypeptides are related to the claims of Examiner's Group II-VIII, which are drawn to methods of using dorsalin-1 polypeptides. Therefore, the claims of Examiner's Groups I and II-VIII are related.

Applicants therefore respectfully assert that two or more independent and distinct inventions have not been claimed in the subject application because the groups are not independent under M.P.E.P. §802.01. Therefore, restriction is improper under 35 U.S.C. §121.

Additionally, applicants point out that under M.P.E.P. §803, the Examiner must examine the application on the merits, even though it includes claims to distinct inventions, if the search and examination of an application can be made without serious burden. There are two criteria for a proper requirement for restriction, namely (1) the invention must be independent and distinct; AND (2) there must be a serious burden on the Examiner if restriction is not required.

Applicants maintain that there would not be a serious burden on the Examiner if restriction were not required. A search of prior art with regard to Group I, dorsalin-1 polypeptides, will reveal whether any prior art exists as to uses of dorsalin-1 polypeptides (Groups II-VIII). Since there is no burden on the Examiner to examine Groups I-VIII in the subject application, the Examiner must examine the entire application on the merits.

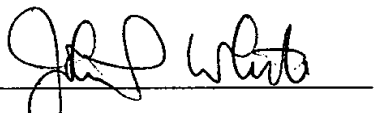
Applicants maintain that claims 17, 19, 20, 22-27 and 36-47 define a single inventive concept. Accordingly, applicants respectfully request that the Examiner reconsider and withdraw

the restriction requirement and examine claims 17, 19, 20, 22-27 and 36-47 on the merits.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorney invites the Examiner to telephone him at the number provided below.

No fee, other than the enclosed $55.00 fee for a one-month extension of time, is deemed necessary in connection with the filing of this Communication. However, if any additional fee is required, authorization is hereby given to charge the amount of such fee to Deposit Account No. 03-3125.

Respectfully submitted,



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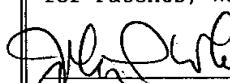
I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231.



3/14/03

John P. White — Date
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